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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,764	09/27/2006	Carl Ralph Flannery	19003-002US1 AM101404	5330

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,764	FLANNERY ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 19-21, drawn to the polypeptide of SEQ ID NO: 9.

Group 2, claim(s) 1 and 19-21, drawn to the polypeptide of SEQ ID NO: 13.

Group 3, claim(s) 1 and 19-21, drawn to the polypeptide of SEQ ID NO: 17.

Group 4, claim(s) 1 and 19-21, drawn to the polypeptide of SEQ ID NO: 21.

Group 5, claim(s) 1 and 19-21, drawn to the polypeptide of SEQ ID NO: 25.

Group 6, claim(s) 2-4 and 33, drawn to the polypeptide of SEQ ID NO: 26 linked to 1-198 repeats of SEQ ID NO: 27.

Group 7, claim(s) 5, drawn to a polypeptide comprising SEQ NO: 26, SEQ ID NO: 28, SEQ ID NO: 29 and 8-28 repeats of SEQ ID NO: 27.

Group 8, claim(s) 6, 13, 28 and 29, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 9.

Group 9, claim(s) 6, 13, 28 and 29, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 13.

Group 10, claim(s) 6, 13, 28 and 29, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 17.

Group 11, claim(s) 6, 13, 28 and 29, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 21.

Group 12, claim(s) 6, 13, 28 and 29, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 25.

Group 13, claim(s) 7-9 and 34, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 26 linked to 1-198 repeats of SEQ ID NO: 27.

Group 14, claim(s) 10, drawn to a polynucleotide encoding a polypeptide comprising SEQ NO: 26, SEQ ID NO: 28, SEQ ID NO: 29 and 8-28 repeats of SEQ ID NO: 27.

Group 15, claim(s) 11, drawn to the polypeptide of SEQ ID NO: 7.

Group 16, claim(s) 11, drawn to the polypeptide of SEQ ID NO: 11.

Group 17, claim(s) 11, drawn to the polypeptide of SEQ ID NO: 15.

Group 18, claim(s) 11, drawn to the polypeptide of SEQ ID NO: 19.

Group 19, claim(s) 11, drawn to the polypeptide of SEQ ID NO: 23.

Group 20, claim(s) 12, 14-18, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 7.

Group 21, claim(s) 12, 14-18, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 11.

Group 22, claim(s) 12, 14-18, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 15.

Group 23, claim(s) 12, 14-18, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 19.

Group 24, claim(s) 12, 14-18, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 23.

Group 25, claim(s) 22-27, drawn to a method of treating a soft tissue of a subject, comprising administering the polypeptide of SEQ ID NO: 9.

Group 26, claim(s) 22-27, drawn to a method of treating a soft tissue of a subject, comprising administering the polypeptide of SEQ ID NO: 13.

Group 27, claim(s) 22-27, drawn to a method of treating a soft tissue of a subject, comprising administering the polypeptide of SEQ ID NO: 17.

Group 28, claim(s) 22-27, drawn to a method of treating a soft tissue of a subject, comprising administering the polypeptide of SEQ ID NO: 21.

Group 29, claim(s) 22-27, drawn to a method of treating a soft tissue of a subject, comprising administering the polypeptide of SEQ ID NO: 25.

Group 30, claim(s) 29-31, drawn to a method of purifying the polypeptide of SEQ ID NO: 26 linked to 1-198 repeats of SEQ ID NO: 27 from cell culture medium.

Group 31, claim(s) 32, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 9.

Group 32, claim(s) 32, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 13.

Group 33, claim(s) 32, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 17.

Group 34, claim(s) 32, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 21.

Group 35, claim(s) 32, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 25.

Group 36, claim(s) 35, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 26 linked to 1-198

repeats of SEQ ID NO: 27.

The inventions listed as Groups 1-36 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the 36 groups of inventions is a lubricin protein.

The inventions of Groups 1-36 do not share the common special technical feature of a lubricin protein, because Swann et al. ("The molecular structure of lubricating glycoprotein-I, the boundary lubricant for articular cartilage," J Biol Chem 256(11):5921-5925, 1981) disclose a lubricin protein, LGP-1 (see p. 5921).

Thus, the technical feature of a lubricin protein does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear that the claims of Groups 1-36 lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the

manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and multiple processes, only a particular combination of which including Group 1 may be considered for unity of invention, i.e., Group 1 and Group 25, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups 1 and 25 cannot be considered to have unity of invention.

Regarding the different claimed sequences, Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of the polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even <u>two</u> different polypeptides or

polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If Applicants elect Group 6, in claim 2, Applicants must elect one definite number for N.

b) If Applicants elect Group 7, in claim 5, Applicants must elect one definite number for N.

c) If Applicants elect Group 13, in claim 7 (pertaining to claim 2), Applicants must elect one definite number for N.

d) If Applicants elect Group 14, in claim 10 (pertaining to claim 5), Applicants must elect one definite number for N.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a

claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 2 and 5.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Claims 2 and 5 recite very large groups of different polypeptides, each of which has a different structure and different biological and chemical properties. That each polypeptide has the same functional properties and activities is not clear from the different sequences or the specification. Each polypeptide is encoded by a different polynucleotide. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR

1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept.

11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25

> total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652 Rosanne Kosson

rk/2007-06-19

/Rebecca Prouty/
Primary Examiner
Art Unit 1652